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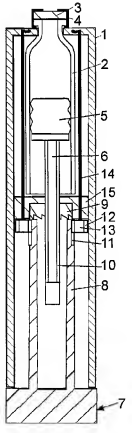
(54) **Title:** AN INJECTION DEVICE



(57) **Abstract:** An injection device for injecting set doses from an ampoule (2) mounted in the device, which doses are set by operation of a dose setting button (7) by which operation elastic torsion rods (14) positioned parallel with the longitudinal axis of the device are twisted. By the dose setting a torque is transmitted from the dose setting button (7) to the rods (14) through gear transmissions comprising a toothing (11) carried by a tubular (8) part coupled to the dose setting button (7) to rotate with this button. The toothing (11) engages pinions (13) fixed to the proximal ends of the torsion rods (14), which are made from a super elastic material, which can stand a deformation larger than 2 % without being permanently deformed.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AN INJECTION DEVICE

The invention relates to injection devices for injecting set doses from an ampoule mounted in the device, which doses are set by operation of a dose setting button by which operation an elastic member is deformed to store an amount of energy which can be released to inject the set dose.

Syringes are known in which a helical spring is compressed to store energy sufficient both for automatic insertion of a needle into the skin of a user and for injection of a set dose through the inserted needle. As the force delivered by such a spring is proportional with the compression and the first part of the expansion when the spring is released is used for insertion of the needle whereas the later part of the expansion is used for the injection of the set dose from the ampoule, the characteristic of the spring must be chosen as a compromise which allow both functions.

In US 5,320,609 separate coil springs are used for the two purposes so that each spring can be chose with the characteristic which is best for its purpose. A dose setting mechanism is so designed that setting of a dose results in a compression of the injection spring which compression can be released to perform the injection. A sequencing mechanism takes care that the injection is not made until the needle has been inserted into the skin of the user by decompression of the needle insertion spring.

Apparatuses are known which uses the same helical spring for both the needle insertion and the injection of medicine but benefits from the fact that a coil spring has different characteristics depending on the way it is used either as a source of an axial force provided by axial compression of the spring or as a source of a torque provided by rotating one end of the coil relative to the other about the longitudinal axis of the coil.

In both the above mentioned devices the characteristics of the injection springs are such that the spring force increases proportionally with the deformation so that the injection pressure will be initially be high and then fade out during the injection.

In US 5,478,316 is described a device in which a constant force spring is provided for exertion of the injection force on the piston. The spring has the shape of a rolled up strip and the spring force is provided as the strip seeks to roll up on the roll again.

All the springs mentioned changes their dimensions during use as one part of the spring is moved relative to the other. By coil springs the ends of the coil is pressed towards each other and space must be made for the expansion of the spring. When the ends of the coil spring are rotated relative to each other the diameter of the coil changes and space must be made to allow such changes. By the constant force spring described the spring strip roll is moved relative to the end drawn off the roll and space must be made for this movement. The syringe housing must encompass all the space mentioned and this way said space contributes to an enlargement of the dimensions of the syringe. As slim syringes are aimed at, it may be seen as a way to enable minimising of a syringe if the space needed for the function of an injection spring is minimised.

According to the invention an injection device as described in the opening of this application is characterised in that the elastic member is a torsion rod which is twisted by the operation of the dose setting member.

The torsion rod may be placed parallel with the longitudinal axis of the syringe with its distal end fixed relative to the syringe housing, and the toque may be transmitted from the dose setting button to the proximal end of the rod by a gear transmission.

The gear transmission may appropriately be established by a toothing carried by the dose setting member to rotate with this member, which toothing engage a gear wheel fixed to the proximal end of the torsion rod. The toothing carried by the dose setting member may appropriately have a larger diameter than has the gear wheel at the proximal end of the rod.

In the following the invention is described in further details with reference to the drawing, wherein

Figure 1 schematically show a sectional view of a syringe provided with torsion rods according to the invention.

The syringe comprises a housing 1 accomodating an ampoule 2 which is at a distal end closed by a rubber membrane 3 sealingly held against a flange by a metal cap 4 at said distal end of the ampoule 2. A not shown needle hub with a needle can be mounted onto the syringe so that one end of the needle penetrates the rubber membrane to communicate with a medicament contained in the ampoule whereas the other end of the needle can be inserted into the skin of a person, who is going to receive an injection.

A piston 5 closing the proximal end of the ampoule 2 can be pressed further into the ampoule by a piston rod 6 to eject a portion of the content of the ampoule through the said needle. The size of the portion can be set by rotating a dose setting member 7 in a clockwise direction over an angle corresponding to the dose one wants to set, which dose is consecutively injected by rotating back the dose setting member 7 to its original position.

The dose setting member is provided with a tubular part 8 which has at its distal end a toothed rosette cooperating with a corresponding rosette on a driver nut 9 so that during the clockwise rotation of the dose setting member, the saw teeth of the dose setting member rides over the saw teeth of the driver nut 9, whereas during the anticlockwise rotation of the dose setting member 7 the teeth of this member engages the teeth of the driver nut 9 to rotate this nut.

The nut 9 has an inner thread engaging an outer thread 10 on the piston rod 6. The nut is rotatable but not lengthwise displaceable in the housing 1 and consequently rotation of the nut 9 will cause the piston rod 6 to move in its longitudinal direction as this rod is not rotatable but longitudinal displaceable. The toothings of driver the nut and of the part 8 of the dose setting member 7 forms a unidirectional coupling which allows the nut to be driven in a direction which causes the piston rod 6 to be moved further into the ampoule when the dosing member is returned to its original rotational position. This is a common construction for injection devices by which a dose can be set and subsequently injected.

In the device according to the invention the tubular part 8 of the dose setting member 7 is at its distal end along its perimeter provided with gear teeth 11 to form a gear which is engaged by the teeth 12 of a pinion 13 which is mounted at a proximal end of a torsion rod 14 the distal end of which is moulded into the housing 1 or in another way fixed to that housing. Adjacent to the pinion 13 the torsion rod is supported by a member 15 which further has a not

round central opening through which the piston rod 6 having a similar not round cross section fits. The member 15 is fixed to the housing 1.

When a dose is set by clockwise rotation of the dose-setting member 7, the toothing on the tubular part 8 will drive the pinion 13 whereby the proximal end of the torsion rod 14 is rotated relative to the distal end of this rod. Thereby a spring force is stored in the torsion rod 14 which spring force will try to rotate said proximal end back to its original position. When a dose is set energy is stored in the torsion rod 14 which energy can be used to perform the rotation of the nut 9, which is necessary to inject the set dose.

A not shown pawl mechanism can be provided, which keeps the dose setting member 7 in its position when it is rotated to set a dose. Was it not for the pawl, the spring force of the torsion rod would immediately rotate the member 7 back and inject the set dose. Now the dose can be set before the needle is inserted into the skin of the person who is going to receive the injection, and when the pawl is thereafter released, the torsion rod will via the pinion 13, the tubular part 8, and the unidirectional coupling between the this tubular part 8 and the nut 9 drive this nut to advance the piston rod into the ampoule to inject the set dose.

In the device shown in figure 1 two torsion rods are shown, each with a pinion engaging the toothing 11 of the tubular part 8 of the dose setting member 7. The device must comprise at least one torsion rod, but if wanted it can comprise two or more torsion rods which are positioned parallel with the longitudinal axis of the ampoule distributed along the perimeter of this ampoule.

The gear toothing on the tubular part 8 can be provided closer to the distal end of this part. This will allow the use of longer torsion rods. The torsion rods can be supported in longitudinal channels in the housing and they may be made of a super elastic material, i.e. a material which allows a deformation larger than 2% without being permanently deformed, which will allow a heavier winding of the rods. Further the rods can be pre-stressed so that they posses some stored spring energy even before they are wound due to the dose setting. This will ensure a safe return of the dose setting member 7 to its original position which must be defined by a stop to avoid that the member 7 is rotated further backward than to its original position.

CLAIMS

1. An injection device for injecting set doses from an ampoule mounted in the device, which doses are set by operation of a dose setting button by which operation an elastic member is deformed to store an amount of energy which can be released to inject the set dose, characterised in that the elastic member is a torsion rod which is twisted by the operation of the dose setting member.

2 An injection devices according to claim 1, characterised in that the rod is positioned parallel with the longitudinal axis of the device.

3. An injection devices according to claim 2, characterised in that a torque is transmitted from the dose setting button to the rod through a gear transmission.

4. An injection device according to claim 3, characterised in that the gear transmission comprises a toothing carried by the dose setting member to rotate with this member, which toothing engage a pinion fixed to the proximal end of the torsion rod.

5. An injection device according to claim 4, characterised in that the toothing carried by the dose setting button has a larger diameter than has the pinion at the proximal end of the rod.

6. An injection device according to anyone of the preceding claims, characterised in that the torsion rod is made from a super elastic material which can stand a deformation larger than 2% without being permanently deformed.

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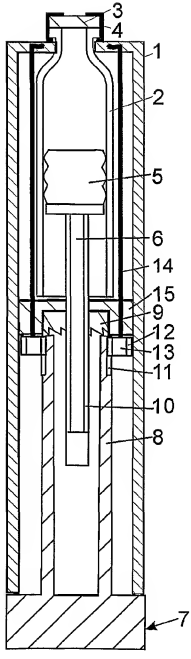

Fig. 1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 01/00337

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/145, A61M 5/20
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0462508 A1 (ISHIKAWA TOICHI), 27 December 1991 (27.12.91) --	1-6
A	EP 0666084 A2 (BECTON DICKINSON AND COMPANY), 9 August 1995 (09.08.95) --	1-6
A	WO 9413343 A1 (HABLEY MEDICAL TECHNOLOGY CORPORATION), 23 June 1994 (23.06.94) -- --------	1-6

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 August 2001	24 09 2001
Name and mailing address of the International Searching Authority European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel(+31-70)340-2040, Tx 31 651 epo nl, Fax(+31-70)340-3016	Authorized officer JACK HEDLUND/E1s Telephone No.

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Information on patent family members

02/08/01

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